

conventional polyethylene terephthalate high pressure catheter balloons). Following inflation and during subsequent deflation, the balloon returns to its original pre-inflation small diameter without wrinkles, again in the fashion of a low pressure elastic (latex) balloon.

II. RESTRICTION REQUIREMENT

The Examiner has restricted the claims to the following three groups:

Group I: Claims 1-62, 67 and 68 to the catheter balloon.

Group II: Claims 63-66 to a balloon cover

Group III: Claim 69, drawn to the method of making the balloon.

The Examiner further stated with regard to the claims of group I, that an election of species is required as follows: Species A: Figures 8-8A (claims 67-68), Species B: Figures 10A-12C (claims 1-62). Applicants at this time affirm their previous provisional election without traverse of the claims of Group I, Species B (claims 1-62).

III. REJECTION OF CLAIMS 1-13 AND 15-62 UNDER 35 USC 103(a) AS UNPATENTABLE OVER HAMILTON (WO 95/09667) IN VIEW OF RAVENSCROFT, et al. (US 5,766,201).

The Examiner describes that Hamilton teaches a thermoplastic elastomer in combination with a non-compliant structural polymeric material and that Ravenscroft et al. teach that a PTFE strip can be helically wrapped around a balloon. She further states that it is well known in the art that PTFE is a porous material, as stated in Abiuso et al. (US 5,213,576), and that accordingly the present invention is obvious.

Applicants' appreciate the Examiner's summaries and conclusions but disagree as follows. The claims require that the balloon comprises an elastomer and a porous material, the porous material being sealed to render it liquid-tight. This combination is not taught or suggested by the references, either alone or in any combination.

First, Hamilton makes no suggestion of the use of porous material of any kind to make a catheter balloon. Ravenscroft, et al. teach the use of a strip of material which may be PTFE wrapped around the exterior of a balloon, however, the strip is not a fundamental part of the balloon. Further, when a strip of PTFE is used (5:63-67), Ravenscroft et al., add that "...the strip can control expansion by varying wrap parameters or strip construction along its length and plastically stretching , *but the strip does not recover elastically upon deflation*" (italics added). Thus they describe that the strip is plastically deformed during inflation of the balloon and clearly does not recover during balloon deflation. This is entirely contrary to the character of the present balloon. Still further, Ravenscroft et al. do not teach or suggest the use of a porous material such as porous PTFE but rather simply state that the strip can be PTFE. This

is in spite of their recognition that their balloon can be used to deliver polymeric grafts including polymeric grafts of porous PTFE (see, e.g., 2:45-60).

At page 5 of the Office Action, lines 7-8, the Examiner states that "It is well known in the art that PTFE is a porous material as stated in Abiuso et al. (2:12-16). This is not correct in that PTFE is not inherently porous. Indeed, conventionally, it is not porous at all. Abiuso et al. refer to Gore-Tex®, which is a form of PTFE intentionally made to be porous by a special process that involves rapid stretching of a PTFE extrusion within specified temperature ranges, see, e.g., US 3,953,566 to Gore, incorporated by reference into the present application (p. 4, lines 6-8). Conventional, non-porous PTFE has a density of about 2.2 g/cc, while porous PTFE, particularly in the form of porous expanded PTFE as described by Gore (ePTFE), typically has densities in the range of 0.5-1.2 g/cc. With regard to Abiuso, et al., they teach the use of porous materials in their balloon construction in order to delivery of a medicant through the pores of the balloon to the surrounding biological structure into which the balloon is inserted. Thus Abiuso et al. clearly teach away from the present balloon wherein the porous structure is sealed. Sealing of the porous material of the balloon of Abiuso et al. would destroy its intended purpose of delivery of a medicant through pores of the balloon material.

Thus, in summary, the only cited reference that teaches a porous material is Abiuso et al., who teach away from a porous structure that is sealed and therefore impermeable with regard to delivery of their intended medicant through the wall of the balloon.

The present balloon is unique in that it is made from a composite of a porous material and an elastomeric material sealed to render it liquid-tight. The balloon offers the expansion and recovery properties of an elastic balloon and the high strength of inelastic balloon. The cited references, as described above, do not teach or suggest the claimed invention.

IV. ALLOWABLE SUBJECT MATTER

Applicants appreciatively acknowledge the patentability of dependent claim 14, but would prefer to defer rewriting that claim in independent form until a further determination is made as to the patentability of the remaining claims.

CONCLUSION

Applicants submit that their claims are patentable over the cited art and are in condition for allowance. Accordingly, Applicants respectfully request reexamination and passage of the claims to issuance.

If any issues of substance are seen to remain following consideration of the arguments presented herein, in the interest of expedient resolution the Examiner is requested to telephone the Applicants' representative at the telephone number given below, between the hours of 8AM to 5PM Mountain Standard Time.

Respectfully submitted,

A handwritten signature in black ink, reading "Wayne D. House". The signature is fluid and cursive, with the first name "Wayne" being more prominent.

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